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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,373	07/24/2003	Peter C. R. Emtage	NUVO-05	3221

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NUVELO, INC
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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,373	EMTAGE ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, and 23-27, 48 and 49, drawn to nucleic acids including vectors, host cells, and arrays, classified in class 536, subclass 23.1.

II. Claims 10, 11, 20-22, and 47, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 12, 30-32, and 46, drawn to an antibodies, classified in class 530, subclass 387.1.

IV. Claims 13-15, and 44, drawn to methods for detecting polynucleotides, classified in class 435, subclass 6.

V. Claims 16 and 45, drawn to methods for detecting polypeptides, classified in class 435, subclass 7.1.

VI. Claims 17 and 18, drawn to methods for identifying compounds that bind to a polypeptide, classified in class 436, subclass 501.

VII. Claim 19, drawn to a method for producing polypeptides, classified in class 435, subclass 69.1.

VIII. Claim 28 and 37 in their entirety, and claims 40 and 42 in part as they would include administering a JPL polypeptide, drawn to methods of treatment that involve the administration of a polypeptide, classified in class 424, subclass 184.1.

IX. Claims 29, 33-36, and 41 in their entirety, and claims 40 and 42 in part as they would include use of an antibody, drawn to a methods of treatment comprising administering an antibody, classified in class 424, subclass 130.1.

X. Claims 39 in its entirety, and claims 40 and 42 in part as they would include use of a cell comprising a nucleic acid of SEQ ID NO: 3, drawn to methods of killing or inhibiting the growth of cells comprising administering an antigen-presenting cell comprising a nucleic acid that encode a JPL polypeptide, classifiable in class 424, subclass 93.21.

XI. Claim 38 in its entirety, and claims 40 and 42 in part as they would include use of a nucleic acid of SEQ ID NO: 3, drawn to methods of killing or inhibiting the growth of cells comprising administering a nucleic acid of SEQ ID NO: 3, classified in class 514, subclass 44.

2. It is noted that claims 46 – 49 are non-statutory use claims (see MPEP 2173.05(q)). Upon amendment of the language of these claims to create statutory subject matter, further restriction may be required.

3. Claim 43 links the separate and distinct inventions characterized by the different methods to detect or measure the expression of JPL protein. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be

entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Further restriction required

4. If applicants elect group I, then applicants should further select a single SEQ ID NO from those recited in claim 23 (either SEQ ID NO: 1 or 2 or 3). Only claims which require the selected SEQ ID NO: will be examined, and claim 23 will only be examined to the extent that it requires the selected SEQ ID NO. Non-elected subject matter will be required to be deleted prior to allowance.

The inventions are distinct, each from the other because of the following reasons:

5. The inventions of groups I, II and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures

including alpha helices and beta-pleated sheets. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by the methods of at least group IV. The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) are associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Group I, II, and III can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

6. Invention I is related as product and process of use with inventions IV, VII, X and XI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in a variety of processes as exemplifired by inventions IV, VII, X and XI, and additionally could be used as a capture probe to affinity purify complementary nucleic acid, or in a nuclease protection assay.

7. Invention I is unrelated to inventions V, VI, IIIV, and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions V, VI, IIIV, and IX neither recite nor require the specific nucleic acids of invention I.

8. Invention II is unrelated to inventions IV, IX, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of invention II are neither recited nor required for the methods of inventions IV (nucleic acid detection), IX (treatment using antibodies), X (treatment using recombinant cells), or XI (treatment using nucleic acid).

9. Invention II is related as product and process of use to inventions V, VI, and VIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

polypeptides of invention II can be used in different method, as evidenced at least by the methods cited herein, or to raise antibodies, for example.

10. Inventions VII and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of invention II can be obtained via other processes, such as isolation from a natural source, or by chemical synthesis.

11. Inventions III and inventions IV, V, VI, VII, VIII, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the antibodies of invention III are neither recited nor required by the cited methods of inventions IV, V, VI, VII, VIII, X, and XI.

12. Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention III can be used in a method other than the therapeutic methods of group IX, such as using the antibody for the purification of protein from a native source.

13. Inventions IV, V, VI, VII, VIII, IX, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation (e.g.: inventions VIII, IX, X, and XI comprise administration of polypeptides, antibodies, cells, and nucleic acids, respectively). Further, the methods have different functions, e.g.: detection of different types of molecules (inventions IV, V, and VI), production of particular molecules (invention VII), and therapeutic functions (inventions VIII, IX, X, and XI).

14. With regard to the further restriction required between individual sequences for group I (claim 23), these sequences are unrelated because they are composed of unique nucleotide sequences and therefore do not share a common structure. A reference against one would not obviate the other, and thus for each particular sequence a separate search of the patent and non-patent literature would be required.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I - XI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER